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| 10/665,864 | 09/18/2003 | Zhuyin Julie Li | USA V2002/0121 US NP | 8381 |
| 5487 7590 06/12/2007 ROSS J. OEHLER SANOFI-AVENTIS U.S. LLC 1041 ROUTE 202-206 MAIL CODE: D303A | | | EXAMINER | |
| | | | KIM, TAEYOON | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s) | |
|-----------------|--------------|---|
| 10/665,864 | LI ET AL. | ÷ |
| Examiner | Art Unit | |
| Taeyoon Kim | 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 25 May 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. 🔲 The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: The period for reply expires _____months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPÉP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below): (b) They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 6. Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. For purposes of appeal, the proposed amendment(s): a) will not be entered, or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: Claim(s) objected to: Claim(s) rejected: 1-25. Claim(s) withdrawn from consideration: _____. AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because: 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). 13. Other: _____.

een B Lankford, Jr

Primary Examiner

Art Unit 165

Continuation of 3. NOTE: The proposed amendement filed on 5/25/07 introduced a new scope to the claims by changing "comprising" into "consisting essentially of", and therefore it requires further consideration and/or search. At the same time, the new scope introduces a new matter situation because there is no support in the specification of the transitional language of "consisting essentially of".

Applicant asserted in the response that the examiner agrees that the instant invention has advantages over other PARP assays (second paragraph of the Remarks filed on 5/25/07). The examiner would like to make it clear that the examiner did not agree or disagree with such assertion in the previous office action. Rather it was mere citation of the sentence from the specification of the current application.

Applicant argued that the advantage of the current invention over the prior art, and such advantage would be considered as unexpected results which need not to be claimed. In ther previous office action, the examiner pointed out that the argument made by the application that the current invention is faster than the prior art is not proper since the current invention claimed the duration of incubation step (a) as indefinite. (e.g. at least about 10 minutes; at least about 2 hours) Therefore, under such claiming language, the current invention cannot be considered as significantly faster than the method of prior art. Thus, the assertion of faster incubation time, and hence faster assay duration, compared to the prior art cannot be considered as "advantage" of the current invention.

Applicant argued that all the references cited in the previous office action failed to teach or suggest all limitations and there is no suggestion or motivation to modify or combine reference teachings to produce claimed invention. The examiner respectfully disagrees with this assertion. This is because Decker et al. (major reference for 35 U.S.C.§103 rejection) clearly teach the limitations of steps in the current invention except the use of fluorescently labeled NAD+. The use of antibody against NAD+ used in the Decker et al's method is one of several detection methods commonly used in the art. Furthermore, the use of labeled NAD in a quantification assay taught by Corominas et al. clearly suggest that labeled NAD can be used in such assay to quantify PARP activity. A person of ordinary skill in the art would recognize fluorescence labe as one of various different ways to label a target molecule to be quantified, and further Amstrong et al. teach the use of fluorescently labeled NAD. Therefore, a person of ordinary skill in the art would have been motivated to use fluorescently labeled NAD for the detection of PARP in the assay of Decker et al. Therefore, the references cited in the previous office action clearly provide motivation for a person of ordinary skill in the art to modify a detection system from using antibody against NAD to using fluorescently labeled NAD. Further a person of ordinary skill in the art would recognize fluorescence labeling as an alternative/equivalent method step as the immunological detection system using an antibody of Decker et al.M.P.E.P. §2144.07 states "The selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945) (Claims to a printing ink comprising a solvent having the vapor pressure characteristics of butyl carbitol so that the ink would not dry at room temperature but would dry quickly upon heating were held invalid over a reference teaching a printing ink made with a different solvent that was nonvolatile at room temperature but highly volatile when heated in view of an article which taught the desired boiling point and vapor pressure characteristics of a solvent for printing inks and a catalog teaching the boiling point and vapor pressure characteristics of butyl carbitol. "Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle." 325 U.S. at 335, 65 USPQ at 301.)". Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call-800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim Patent Examiner Art Unit 1651